REMARKS

Claims 1-8, 10, 12-14 and 19 are pending in this application. By this Amendment the specification is amended. No new matter is added.

I. Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1-8, 10, 12-14 and 19 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

In addition to rejecting the claims, the Patent Office alleges that the specification also does not comply with the requirements of 35 U.S.C. §112, first paragraph, because trademarks are used without sufficiently describing the goods associated with such trademarks. Applicants disagree with the Patent Office's allegations, but have amended the specification to further describe the goods associated with OsteoGraf® /N 300 and PEPGEN P-15®.

With respect to the claims, the Patent Office alleges that the specification fails to disclose any bone repair putty materials, other than the disclosed embodiment, that meet the claim limitations of 55 weight percent or greater of a particulate having a bulk density of 1.1 to 1.3 g/cc. The Patent Office alleges that the specification does not provide any guidance as to how to identify other suitable particulate/carrier combinations. Applicants disagree with these allegations.

In rejecting a claim, the examiner must set forth express findings of fact which support the lack of written description conclusion. These finding should identify the claim limitation at issue, and establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. See MPEP §2163.

Applicants submit that the Patent Office has not provided any reasons why one of ordinary skill in the art would not have recognized that the original disclosure provides support for the current claims. A conclusory statement that the specification does not provide any guidance is not sufficient to support a rejection for lack of written description.

Moreover, Applicants submit that the original disclosure provides sufficient guidance to one of ordinary skill in the art as to how to identify suitable particulate/carrier combinations. The skill in the art is extremely high and an extremely detailed description of such combinations is not necessary for one of ordinary skill in the art to recognize that the Applicants had possession of the claimed invention at the time the application was filed. Further, the specification provides examples detailing suitable particulate/carrier combinations.

Applicants discovered that high density particulate could be added at a concentration of 55 weight percent or greater to a resorbable carrier gel. This would form a bone-repair putty having good viscosity and handling properties. As explained in the original specification, a preferred carrier component is a polysaccharide such as hydroxylpropyl cellulose or methyl cellulose or the like. Particularly preferred are mucopolysaccharides, such as hyaluronic acid and its derivatives. The carrier selected is of high molecular weight and in a sufficiently high concentration in the putty to suspend the high concentration of particulate in the putty, said concentration preferably 45-64 mg/cc (see paragraph [0020] of the specification). A key advantage of the carrier is that the particulate, once placed, remains uniformly suspended, does not settle or separate substantially from the carrier, does not significantly swell after placement in a bone defect repair and where particles do not migrate away from putty (see paragraph [0021] of the specification).

The carrier material must be biocompatible, even at relatively high concentrations that are necessary to achieve a formulation that does not excessively change dimensions. Dimensional stability of the formulation, i.e., neither significantly expanding nor shrinking, is also a key feature of the invention (see paragraph [0028] of the specification). The carrier component selected must be present in a relatively high concentration to contain the desired high concentration of particulate and yet maintain desired putty characteristics and retain the particulate at the defect site (see paragraph [0030] of the specification).

When the high-density bone particulate is added at the claimed concentration, the resulting putty has good dimensional stability. The particulate is not allowed to migrate away from the bone repair site and this enhances new bone growth.

From this description in the original disclosure, it is apparent that one of ordinary skill in the art would have understood that the Applicants had possession of the claimed invention at the time the application was filed. The original disclosure clearly provides sufficient description of the bone particulate, the carrier and the interaction between the particulate and carrier, such that one of ordinary skill in the art would have understood, at the time of filing, that the Applicants were in possession of the invention as presently claimed.

For the foregoing reasons, Applicants submit that claims 1-8, 10, 12-14 and 19 comply with the written description requirement. Reconsideration and withdrawal of the rejection are respectfully requested.

II. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-8, 10, 12-14 and 19 are requested.

The Examiner is invited to contact the undersigned at the telephone number below with any questions.

Respectfully submitted,

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